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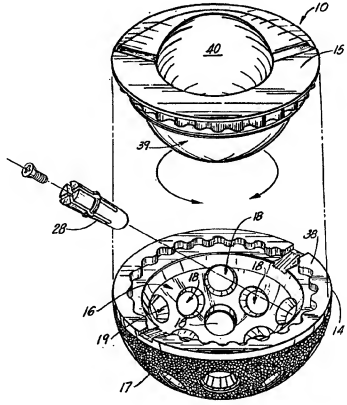
(57) Abstract

An improved orthopedic joint prosthesis (10) has a prosthesis body (14) having a first surface (17) for engaging a patient's joint and a second surface (16) for receiving a polymeric liner (15). The second surface (16) is highly polished or mirror-like, for retarding debris generating from the polymer liner (15) and also allows optical pattern inspection.



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"ORTHOPEDIC PROSTHESIS"

The present invention relates to orthopedic prosthetic joint devices for implantation into or replacement of a joint of the human or animal body.

A number of commercially available prosthetic devices for implantation into a patient's joint or for total joint replacement include a metallic part and a plastics liner forming at least in part, the articulating surface of the joint. For example, in US Patent No. 4,828,565 there is provided a cotyliodal component for a non-cemented hip prosthesis. The component has two parts, a titanium hemispherical shell and a cup of polymer which is engaged into it.

Other patents and patent applications which describe acetabular cups include European Patent Application No. 212,087 published April 3, 1987, wherein metallic pins project from the surface of the cup and contain holes in which tissue may grow. In European Patent No. 341,198 published November 8, 1989, an acetabular cup has a metal outer shell and a plastic body for retaining the hip joint head.

The use of a combination of a plastics liner and a base member is also a feature of other joint prostheses such as those for implantation into the shoulder or knee. One example of a tibial prostheis which has a plate or insert forming an

articulating surface for the joint is described in US Patent No. 4462120.

The present invention provides an improved orthopedic joint prosthesis wherein the prosthesis body has a base member (e.g. tray, cup or shell) and a polymeric liner. The polymeric liner affixes to the prosthesis body and provides an articulating surface for engaging another prosthesis member.

The prosthesis body has a non-articulating mirrored or polished surface that receives the plastic liner. This surface has a polished surface that faces the liner for retarding liner debris generation. The polished surface has a roughness of preferably less than eight (8) micro-inches.

The combination of the polymeric liner and orthopedic base with mirrored or polished surface finish provides numerous advantages. First, it provides a low friction and low abrasion surface for distributing the contact forces between the polyethylene liner (e.g., UHMWPE) and the prosthesis body shell. This reduces the abrasive generation of polyethylene debris resulting from motion between the liner and the body.

This motion may come from a variety of mechanisms which include Poisson volumetric distortion of the polyethylene resulting in

localized expansion and contraction of the surface of the liner against the body as a result of loading the liner, and the micro-motion which occurs from forces from a liner within and around the confines of the prosthesis body interior. For example, in the case of an actabular prosthesis, the femoral head is loaded at the liner.

Micro-motion can occur in hip prosthesis from forces generated by the femoral head pushing the liner within and around the confines of the prosthesis body, namely an acetabular cup body with a concave polished surface that receives the liner. Micro-motion can occur in a knee prosthesis as a tibial tray liner receves force generated by a femoral prsthesis. A shoulder or glenoid component also has force transmitted at the joint to a plastic liner of the glenoid metallic component.

The mirror finish also allows the use of optical non-contact inspection of the interior of the metallic component surface for checking the geometric correctness of the component. The use of non-contact optical inspection methods allow complete checking of whole two and three dimensional surfaces at one time. The usual method of optical three-dimensional inspection is to project a regular pattern of light onto the surface which is to be inspected. The resultant two dimensional projection of the scene may be used to give highly accurate total surface measurement.

Distortions in the regular pattern indicate distortions in the part surface and indicate deviations from the desired part geometry. This method is ineffective on highly smooth surfaces since the projected light of the regular pattern bounces off the measurement target and no two dimensional mapping is possible. In this device the highly smooth surface is further polished to act as a reflective mirror. This surface mirror then is used as a lens to view a two-dimensional pattern such as a grid drawn on a white sheet of paper or a series of concentric rings. Distortions in the viewed image then are a result of distortions of the lens and hence the surface which is desired to be measured. It is thereby possible to inspect the highly smooth surface of the prosthesis body due to this polishing.

The method of inspection may be both by trained human inspectors and by image analysis performed by capturing the reflected image by a video camera, digitizing the image, and using computer analysis to measure the amount of deviation of the pattern from the allowed surface geometry tolerance.

The advantages of this smooth and polished surface is therefore to provide non-contact, and therefore non-destructive (non-scratching), measurement of the interior of an acetabular device. The inspection methods require a surface

which allows a reflective resolution sufficient to provide adequate reflective image quality for analysis. Current inspection limits require a surface finish of less than eight (8) micro-inches to accomplish this quality of resolution.

In one embodiment, the present invention provides an improved acetabular prosthesis. For an acetabular prosthesis, an acetabular cup body preferably includes openings therethrough which can function as drill guides for the surgeon after the cup has been placed in the patient's acetabulum.

A second embodiment of the invention is a glenoid prosthesis for implantation into a shoulder.

A further embodiment of the invention may be a knee prosthesis such as those generally used for total knee replacement implants.

BRIEF DESCRIPTION OF THE DRAWINGS:

For a further understanding of the nature and objects of the present invention, reference should be had to the following detailed description taken in conjunction with the accompanying drawings, in which like parts are given like reference numerals, and wherein:

FIGURE 1 is a side sectional view of the preferred embodiment of the apparatus of the present invention showing an acetabular cup;

FIGURE 2 is a side sectional view of the preferred embodiment of the apparatus of the present invention showing an acetabular cup;

FIGURE 3 is an exploded perspective view of the preferred embodiment of the apparatus of the present invention showing an acetabular cup;

FIGURE 4 is a top view of the preferred embodiment of the apparatus of the present invention showing a glenoid component;

FIGURE 5 is a bottom view of the preferred embodiment of the apparatus of the present invention showing a glenoid component;

FIGURE 6 is an elevational view of the preferred embodiment of the apparatus of the present invention showing a glenoid component;

FIGURE 7 is a side view of the preferred embodiment of the apparatus of the present invention showing a glenoid component;

FIGURE 8 is a bottom view of the preferred embodiment of the apparatus of the present invention showing a tibial component;

FIGURE 9 is an elevational view of the preferred embodiment of the apparatus of the present invention taken along lines 9-9 if figure 8, showing a tibial component;

FIGURE 10 is a sectional view taken along lines 10 - 10 of Figure 8;

FIGURE 11 is an elevational view of the preferred embodiment of the apparatus of the present invention showing a tibial component;

FIGURE 12 is a side view of the preferred embodiment of the apparatus of the present invention showing an asymmetric tibial component;

FIGURE 13 is a top view of the preferred embodiment of the apparatus of the present invention showing an asymmetric tibial glenoid component;

FIGURE 14 is an elevational view of the preferred embodiment of the apparatus of the present invention showing an asymmetric tibial component; and

FIGURE 15 is a bottom view of the preferred embodiment of the apparatus of the present invention showing an asymmetric tibial component.

FIGURE 16 is a schematic diagram of the grid used to inspect the polished surface for distortions;

FIGURE 17 is a second embodiment of a test grid pattern used to inspect the highly polished surface portion of the acetabular cup prosthesis of the present invention;

FIGURE 18 is a schematic diagram of a test grid showing no surface defects; and

FIGURE 19 is schematic diagram showing local defects for a polished surface that has been inspected using the grid.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT:

In FIGURE 1 there can be seen a sectional view of the first embodiment of the apparatus of the present invention designated generally by the numeral 10. In FIGURE 1, there can be seen a hip prosthesis member 11 mounted in a femur 12 of a patient. The hip prosthesis 11 includes an upper ball portion 13 that registers with the acetabular prosthetic apparatus 10 of the present invention.

The acetabular prosthesis 10 includes a cup or shell prosthesis body 14, preferably of a metallic material with a plastic liner 15 portion. The metallic cup body 14 includes an inner concave surface 16 and an outer convex surface 17. The surfaces 16, 17 are spaced apart, defining the thickness of the cup or shell 14. The cup body 14 can provide a three-dimensional surface treatment that is sintered to the outside surface 17 (such as sintered metal beads). The surface 17 can be machined after sintering. Another type of roughened outer surface 17 could be provided such as plasma sprayed metal, plasma sprayed hydroxyl apatite, or a mechanically textured or roughened surface. The shell or cup body 14 could have an exterior surface 17 optimized for use with bone cement.

A plurality of openings 18 in form of preferably elongated bores extend between the inner concave surface 16 and the outer convex surface 17. These openings are in the form of bores having a bore wall 19. The openings 18 can function as drill guides for the surgeon. Therefore, once the metallic cup body 14 portion of the acetabular cup prosthesis 10 is placed in position in the patient's acetabulum as shown in FIGURE 1, the surgeon can simply drill through any one of the plurality of bores forming an opening in the underlying bone tissue designated generally be the numeral 20.

When the surgeon places the cup body 14 in the position shown in Figure 1, the plurality of bores 18 can act as a drill guide for the surgeon. The bore 19 walls of each opening 18 can be shaped to define a guide for a correspondingly shaped and sized drill. Openings 18 allow the surgeon to form surgical openings in the underlying bone tissue 20.

A selected surgically formed opening 18 is then occupied by a peg (and not necessarily each opening 18), such as one of the pegs 25 - 28, as seen in Figure 1. In the preferred embodiment, each of the pegs 25 - 28 extends into the bone tissue at a different angular position with respect to the other pegs to provide a rigid anchor for the cup 14. Pegs 25-28 can be polymer, metal, or resorbable polymer. In Figure 2, cup body 14 is secured with a plurality of bone screws 30-33. Each bone screw has a frustroconical section 34 that forms a wedge-lock or taper lock connection with a frustroconical opening or bore 35 in cup body 14 when the threaded shank 36 of each bone screw 30-33 fully engages underlying bone tissue 20.

Cup body 12 is preferably metallic having an annular base 38 that defines a plane (see Figure 3). The cup body 12 concave surface 16 is a shiny polished surface that faces the convex surface 39 of polymeric liner 15. The polished concave surface 16 has a roughness of less than sixteen (16) micro-inches, and preferably less than eight (8) micro-inches. Such a highly polished surface 16 appears mirror-like. The polished concave surface 16 inhibits polymer liner debris generation. Liner 15 has an inner concave surface 40 that receives femur ball portion 13 during use (see Figures 1 and 2).

Figures 4-7, the preferred embodiment of the apparatus of the present invention 10 is shown in the form of a glenoid

prosthesis. The glenoid prosthesis 10 includes a component 41 that can cooperate with a humeral component (not shown). The use of glenoid components is part of a total shoulder system can be seen for example in Smith & Nephew Richards publication entitled "Cofield Total Shoulder System Surgical Technique", and in U.S. Patent 5,108,396, incorporated herein by reference. The glenoid component 41 has a bone ingrowth surface 42 that can be, for example, a plurality of metallic sintered beads 43. Bone ingrowth surface 42 is attached to the patient's bone tissue with bone cement and screws for example as described more fully in the Cofield Total Shoulder System Surgical Technique and in U.S. Patent 5,108,396.

Surface 44 is a mirror surface that receives a polyethylene or like insert that provides an articulating surface for articulating with a humeral component. Thus, the mirror surface 44 is a non-articulating surface that engages the rear or non-articulating surface of the polyethylene insert. The glenoid component can include a stem 45 and cylindrical hollow sleeves 46 that accommodate bone screws. Annular shoulder 47 projects away from mirror surface 44, defining a structure that can hold the polyethylene insert during use.

In Figures 8-11, the preferred embodiment 10 of the apparatus of the present invention is shown in the form of a tibial prosthesis. The tibial prosthesis 10 includes a tibial component 48 having a stem 49 that occupies a surgically formed opening in the patient's tibia. The distal side of tray 51 registers against the patient's proximal tibia, once surgically shaped to receive tibial component 48. Tibial component 48 has a mirror surface 50 that receives polymeric insert 52 (see Figure 11). Mirror surface 50 is provided on the proximal side of tray 51.

During use, polymeric insert 52 articulates with femoral component 53. Femoral component 53 is attached to the patient's femur 54 (as shown in Figure 11), articulating against polymeric insert 52 that is supported upon the mirror surface 50. Surface 50 is the proximal surface of tray 51. Thus, the mirror surface is a non-articulating surface that engages the rear or distal surface of the polymeric insert 52. The proximal surface of polymeric insert 52 is an articulating surface that receives a polished metallic articulating surface of femoral component 53.

In Figures 12-15, the preferred embodiment 10 of the apparatus of the present invention is shown in the form of an asymmetric tibial prosthesis. Prosthesis 10 includes an asymmetric tibial component 56 that has a bone engaging surface 57 that engages the proximal, surgically prepared surface of the patient's tibia. The opposing surface from bone engaging surface 57 is a proximal, mirror surface 58 that receives a polymeric insert (not shown). Peripheral shoulder 59 and mirror surface 58 define non-articulating surfaces that receive the polymeric insert, much in the same fashion that polymeric insert 52 is held with tray 51 at surface 50. An opening 60 allows tibial component 56 to be attached to the patient's tibia using a bone screw, for example.

It should be understood that the attachment of a polyethylene or polymeric insert to a tibial component (such as tray 51), or to an asymmetric tibial component (such as component 56) is per se known in the art. Such inserts are shown and described in the Smith & Nephew Richards publication entitled "Genesis Total Knee System Surgical Technique" published in 1992 and incorporated herein by reference. However, the present invention provides an improvement that features a mirror surface portion in combination with a

polymeric insert as aforedescribed as part of an overall prosthesis 10.

Figures 16-19 grid charts 200, 205 that can be drawn on a white sheet of paper for example and used to inspect the highly polished inner concave surface 16' of acetabular cup body 14 for defects. In Figure 16, a grid 200 is in the form of a plurality of concentric rings 201, 202, 203, etc. A central opening 204 allows the user to visually inspect the inside surface 16 of the cup body 14 when the flat grid 200 is placed on top of the cup body 14 with the print of chart 200 facing the mirror like polished concave surface 16. In this fashion, the user simply views the lined pattern of the concentric rings 201-203 of grid chart 200 as reflected off the mirror surface of the inside, concave surface 16 of the cup body 14.

In Figure 17, a generally rectangularly shaped test grid 205 is shown. In Figure 18, a reflective pattern for the test grid 205 is shown as pattern 206, showing no defects. In Figure 19, another test grid pattern reflection 207 is shown that notes two local defects 208, 209.

Figure 16 illustrates a method of inspection that may be used by trained human inspectors, simply looking through the central opening 204. When such human inspection is employed, the inspector simply looks through the opening 204 when the grid chart 200, 205 is placed against the concave 16 side of acetabular cup body 14.

Another method of inspection may be by image analysis performed by capturing the reflected image with a video camera, digitizing the image and using computer analysis to measure the amount of deviation of the pattern from the allowed surface geometry tolerance. Thus, the surface 16 defines a mirror that is used as a lens to view a two

dimensional pattern such as the grid patterns 200, 205 drawn for example on a white sheet of paper. Distortions in the viewed image are then a result of distortions of the lens surface 16 and hence the surface which is desired to be measured.

The following Table 1 lists part numbers and corresponding part descriptions as used herein and in the drawings:

TABLE 1 - PARTS LIST

PART NUMBER	PART DESCRIPTION
10	joint prosthesis
11	hip prosthesis member
12	femur
13	ball portion
14	cup body
15	plastic liner
16	inner concave surface
17	outer convex surface
18	openings
19	bore wall
20	bone tissue
25-28	pegs
30-33	bone screws
34	frustroconical portion
35	frustroconical bore
36	threaded shank
38	annular base
39	liner convex surface
40	liner concave surface
41	glenoid component
42	bone ingrowth surface
43	metallic beads
44	mirror surface
45	stem
46	hollow bushing
47	annular shoulder
48	tibial component
49	stem
50	mirror surface
51	tray

52	polymeric insert
53	femoral component
54	femur
55	tibia
56	asymmetric tibial component
57	bone engaging surface
58	mirror surface
59	peripheral shoulder
60	opening
200	circular grid pattern chart
201	concentric ring
202	concentric ring
203	concentric ring
204	central opening
205	rectangular grid pattern chart
206	reflective pattern - test grid
207	reflective pattern - test grid
208	defect
209	defect

Because many varying and different embodiments may be made within the scope of the inventive concept herein taught, and because many modifications may be made in the embodiments herein detailed in accordance with the descriptive requirement of the law, it is to be understood that the details herein are to be interpreted as illustrative and not in a limiting sense.

What is claimed as invention is:

Claims

1. An orthopedic joint prosthesis comprising:

a) a prosthesis body having a first body surface for engaging a patient's joint and second body surface, and

b) a polymeric liner that lines the prosthesis body at the second surface during use, the liner having first and second surfaces, the second surface defining an articulating surface that is positioned to receive and articulate with a separate joint prosthesis articulating member, the first side of the liner defining a non-articulating surface that is positioned on the opposite side of the liner from the second surface; characterised in that said body surface of the prosthesis body has a polished surface.

2. An orthopedic joint prosthesis according to claim 1; wherein said polished surface has a roughness of less than eight microinches.

3. The orthopedic joint prosthesis of claim 1 or claim 2 wherein the polished inner surface has a roughness of less than four (4) microinches.

4. The orthopedic joint prosthesis of any of claims 1-3 wherein the polished inner surface has a roughness of between one (1) and four (4) microinches.

5, An orthopedic joint prosthesis according to any of claims 1 to 4, wherein said polished surface is mirror-like.

6. The orthopedic joint prosthesis of claim 5 further comprising grid means for inspecting the polished inner surface for defects.

7. The orthopedic joint prosthesis of claim 6 wherein the grid means is a grid comprised of a plurality of concentric rings.

8. The orthopedic joint prosthesis of either claim 6 or claim 7 wherein the surface mirror defines a lens to view the grid.

9. An orthopedic joint prosthesis according to any of the preceding claims, wherein said polymeric liner comprises polyethylene.

10. An orthopedic joint prosthesis according to any of the preceding claims, wherein said prosthesis is an acetabular cup body prosthesis.

11. An orthopedic joint prosthesis according to any of claims 1-9 wherein said prosthesis is a glenoid prosthesis.

12. An orthopedic joint prosthesis according to claim 11, wherein said glenoid prosthesis comprises a glenoid component including a stem and cylindrical hollow sleeves for accommodating bone screws.

13. An orthopedic joint prosthesis according to any of claims 1-9, wherein said prosthesis is a tibial prosthesis.

14. An orthopedic prosthesis according to claim 13, wherein said tibial prosthesis comprises a tibial component having a stem for implantation

into a tibia and a tray attached to the stem, said polished surface being provided on the tray.

15. An orthopedic prosthesis according to either claim 13 or claim 14, wherein said tibial prosthesis is an asymmetric tibial prosthesis.

16. An orthopedic joint prosthesis according to any of the preceding claims further comprising means for connecting the liner to the prosthesis body such that the non-articulating surface of said liner is adjacent to and in contact with the polished second body surface of the prosthesis body.

17. An orthopedic prosthesis according to claim 16, wherein said means comprises an annular shoulder which projects away from the mirror surface and defines a structure which holds the polymeric insert during use.

18. An orthopedic prosthesis according to claim 16, wherein said means comprise projections on a surface of either the polymeric liner or said non articulating surface which may engage in complementary grooves in the other surface.

19. An orthopedic prosthesis according to claim 16, wherein said means comprises a peripheral shoulder adjacent to said polished surface.

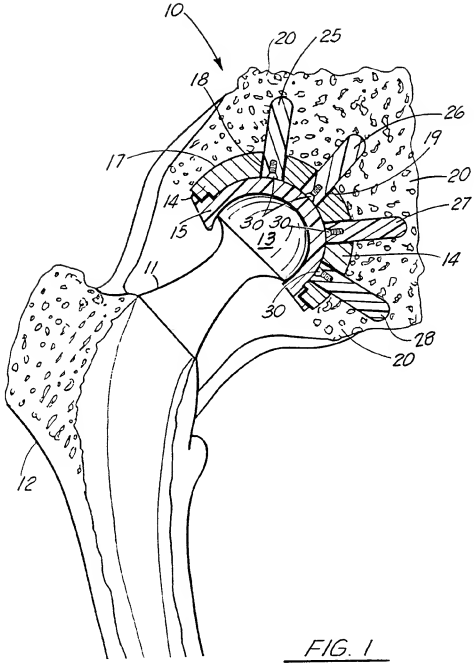

FIG. 1

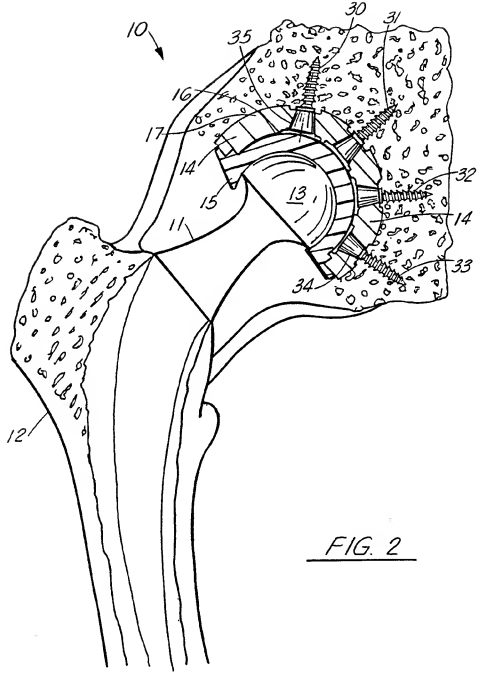

FIG. 2

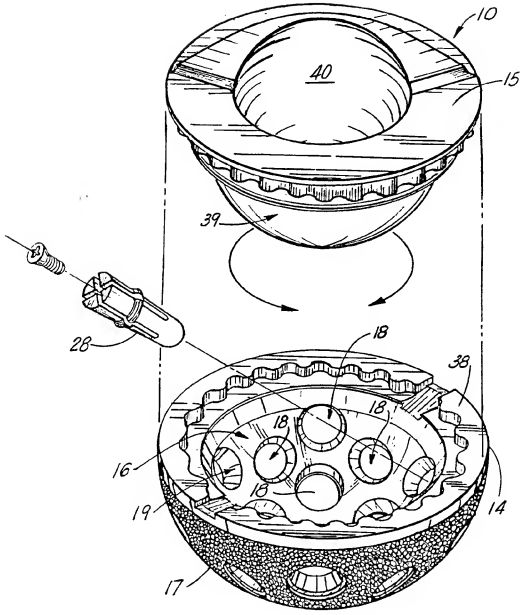

FIG. 3

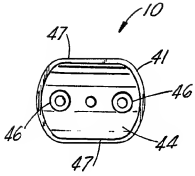

FIG. 4

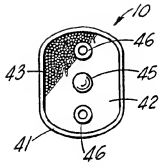

FIG. 5

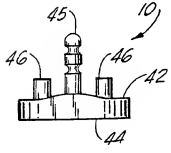

FIG. 6

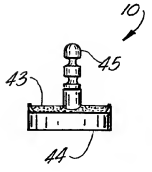

FIG. 7

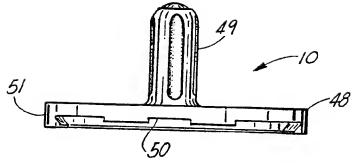

FIG. 9

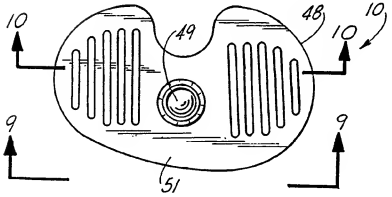

FIG. 8

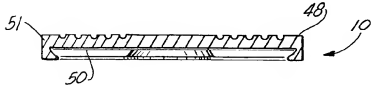

FIG. 10

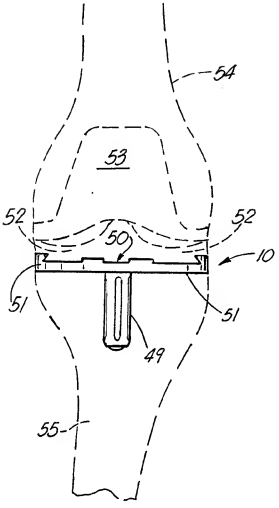

FIG. 11

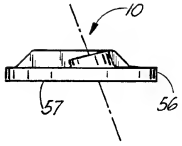

FIG. 12

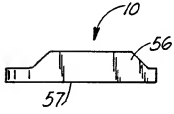

FIG. 14

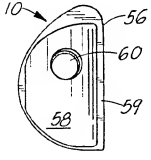

FIG. 13

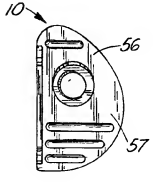

FIG. 15

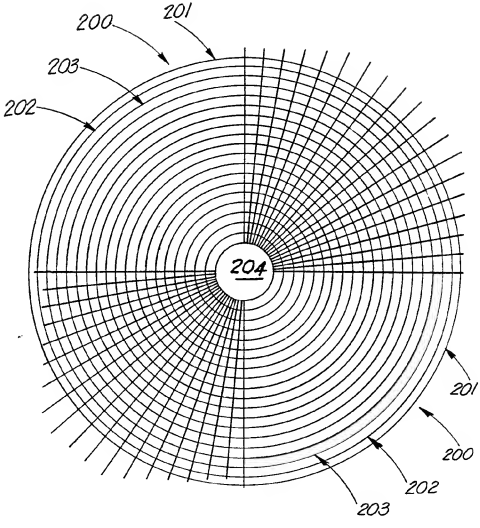

FIG. 16

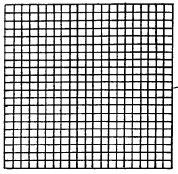

FIG. 17

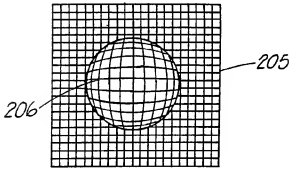

FIG. 18

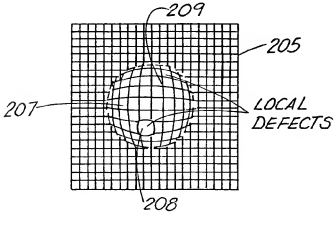

FIG. 19

INTERNATIONAL SEARCH REPORT

In ational application No.
PCT/US95/05710

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/30. 2/32, 2/38, 2/40
US CL :623/18-20, 22, 23

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/18,19,20,22,23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4,770,661 (OH) 13 September 1988, see entire document.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
12 JUNE 1995	05 JUL 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer DAVID J. ISABELLA
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